DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 29, 2016

Micro-Tech (Nanjing) Co., Ltd.
Ms. Becky Li
Quality Director
No. 10 Gaoke Third Road
Nanjing National Hi-Tech, Industrial Development Zone
Nanjing, 210032 CN

Re: K162466
Trade/Device Name: LuminScan™ Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NQQ
Dated: August 31, 2016
Received: September 2, 2016

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162466

Device Name

LuminScan(TM) Imaging System

Indications for Use *(Describe)*

The LuminScan(TM) Imaging System is is indicated for use as an imaging tool in the evaluation of human tissue microstructure by providing two dimensional, cross sectional, real-time depth visualization.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab 7

510 (K) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____ K162466

510 (K) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. **Date of Preparation: 11/24/2016**

2. **Sponsor Identification**

Micro-Tech (Nanjing) Co., Ltd.
No.10 Gaoke Third Road, Nanjing National Hi-Tech, Industrial Development Zone, Nanjing, 210032, Jiangsu Province, PRC
Establishment Registration Number: 3004837686
Contact Person: Becky Li
Position: Quality Director
Tel: +86-25-58646378
Fax: +86-25-58744269
Email: In@micro-tech.com.cn

3. **Identification of Proposed Device**

Product Name: **LuminScan™ Imaging System**
Common Name: **Endoscopic Optical Coherence Tomography Imaging System (EOCT Imaging System)**
Model: **C1**
Regulatory Information:
Classification Name: **Ultrasonic pulsed echo imaging system**
Classification: **Class II**
Product Code: **NQQ**
Regulation Number: **21 CFR892.1560**
Review Panel**: General & Plastic Surgery**

4. Identification of Predicate Device

510(k) Number: **K112770**

Product Name: **Nvision VLE Imaging System (OCT)**

5. Device Description

LuminScan™ Imaging System is a general imaging system comprised of LuminScan™ Imaging System Console and LuminScan™ Disposable Imaging Kit.

6. Indications for Use

LuminScan™ Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure by providing two dimensional, cross sectional, real-time depth visualization.

7. **Clinical Test Conclusion**

This section is not applicable because there is not including any clinical performance data with this 510(k) Submission.

8. Comparison of Technological Characteristics

LuminScan™ Imaging System is an optical coherence tomography (OCT) imaging device, which has similar technological characteristics as the predicate device cleared under 510(k) K112770 of NinePoint Medical Inc. Both devices use the principles of swept source OCT to generate high-resolution, two-dimensional, cross-sectional images of tissue microstructures in real time.

The main technological differences between the proposed device and the predicate device are the inflation method of accessory and the parameters of the accessory. The proposed device use automatic pump to inflate balloon of accessory, and controlled by system software. The predicate device use manual method to inflate balloon. In additional, the diameter of the inflation balloon in the proposed device is 16 mm whereas the diameter in the predicated device is 25 mm. Moreover, the inflated pressure of the inflation balloon in the proposed device is 3 atm whereas the pressure in the predicate device is 0.34 atm. Furthermore, the accessory in the proposed device can pass through the endoscopic channel as small as 2.8 mm. The predicate device

requires an endoscopic channel of no less than 3.7 mm.

With risk mitigation mechanisms in the proposed device, however, these differences between the proposed device and the predicate device in the technological characteristics are minor and would not raise any questions of safety or effectiveness.

Comparison to predicate Device:

Technological Characteristics	Nvision VLE® Imaging System (K112770)	LuminScan™ Imaging System
Intended Use and compatibility:		
Product Code	NQQ	NQQ
Regulation No.	21CFR892.1560	21CFR892.1560
Class	2	2
Supplied Sterile	Yes	Yes
Configuration	Imaging tool and accessory	Imaging tool and accessory
Where Used	Hospital Setting	Hospital Setting
Indications for Use	Imaging tool in the evaluation of human tissue microstructure by providing two-dimensional ,cross sectional , real- time depth visualization	Imaging tool in the evaluation of human tissue microstructure by providing two-dimensional ,cross sectional , real- time depth visualization
Console:		
Radiation Type	Near Infrared	Near Infrared
Optical Source	Swept source laser	Swept source laser
Center Wavelength	1300 nm	1300 nm
Optical Bandwidth	110 nm	120 nm
Optical Radiation Safety	Safe for indicated use, Class 1M laser source	Safe for indicated use, Class 1M laser source
Measurement Technique	OCT, Fourier domain	OCT , Fourier domain
Scanning Mode	Helical pitch (360 degree + 6 cm pullback length)	Helical pitch (360 degree, up to 8 cm pullback length)
Frame Rate	12.5 frames/sec	24.4 frames/sec
Inflation Method	manual	automatic
Optical Probe:		
Optical Fiber Probe Material	Silica and borosilicate glass	Silica and borosilicate glass
Torque Cable and Hypo tube Cap Material	316 SS	304 SS
Optical Probe	Single mode optical fiber with distal optics	Single mode optical fiber with distal optics

Technological Characteristics	Nvision VLE® Imaging System (K112770)	LuminScan™ Imaging System
Probe Dimensions	2.5 m nominal	2.5 m nominal
Guide Sheath:		
Shaft Material	Nylon	Nylon
Balloon Material	PET	Nylon
Guide Sheath	Balloon guide sheath , polymer tubing with closed end	Balloon guide sheath , polymer tubing with closed end
Inflated Diameter	25 mm	16 mm
Inflated Length	72 mm	30/55/80 mm
Inflated Pressure	5 psi (0.34 atm)	3 atm
Sheath Assembly will be Inflated and Deflated Multiple Times	＞10 cycles	＞20 cycles
Balloon Inflation and Deflation Time	＜60 sec	＜60 sec
Endoscopic Channel	3.7mm	≥2.8 mm
Tip structure	Atraumatic tip	Atraumatic tip
Biocompatibility (Body contacting components)	ISO 10993 compatible	ISO 10993 compatible
General Use	Single use and sterile guide sheath and optical probe	Single use and sterile guide sheath and optical probe
Shelf life	6 months	12 months

9. Performance Data

Safety Testing

The product development processes have been shown to conform to product safety standard including:

Safety Testing	Recognized Standard or Guidance
Risk Management	ISO 14971
Medical Electrical Equipment	IEC 60601-1
Electromagnetic Compatibility	IEC 60601-1-2
Application of Usability	IEC 60601-1-6 and IEC62366
Safety of Endoscopic Equipment	IEC 60601-2-18
Laser Safety	IEC 60825-1
Biological Evaluation Of Medical Devices - Ethylene Oxide Sterilization Residuals	ISO 10993-7
Validation and Routine Control of Ethylene Oxide Sterilization process	ISO 11135-1

Safety Testing	Recognized Standard or Guidance
Transport Packaging	ISTA 2A and 2B

Bench Testing

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for the **LuminScan™ Imaging System** was considered as a "Minor" level of concern, since failures or latent design flaws in the software are unlikely to cause any injury to the patient or operator.

Disposable Imaging Kit Testing

The following in-vitro performance tests were completed on the **Disposable Imaging Kit**; all the tests were found to be within their test acceptance criteria (passing test result):

Balloon Diameter	Balloon length
Balloon Burst Testing	Balloon Fatigue Testing
Balloon Inflation/Deflation Testing	Tensile Strength
Endoscopic Compatibility Testing	Airtightness
Retraction testing	Sterilization and Shelf Life Testing
Biocompatibility Testing	

Reliability Testing

Device reliability was evaluated against several environments factors (e.g., temperature, humidity) when the product was in operation or was properly stored. In additional, vibration testing was performed to evaluate the device reliability when the product was power off. Both tests yielded passing results.

System Performance Testing

High-level product design requirements of the **LuminScan™ Imaging System** were evaluated in system performance testing. System performance yielded a passing test result.

Animal Testing

Animal testing was performed to evaluate imaging procedure as well as image quality

to ensure that the device meets the design requirements as intended.

An animal testing summary is provided in the following table:

Item	Description
Species	Bama miniature pig (*Sus scrofa domesticus*)
Quantity	2
Sex	One male and one female
Age	8-9 months
Weight	35-40 kg
Imaging Anatomical Area	Esophagus
Obtained Images	Two-dimensional and cross-sectional OCT images of animal esophagus were captured by the device. User could review the images with replay function. User could select region of interest (ROI) on the cross-sectional images and show zoomed-in image of ROI. User could make marker on the images and take a snapshot of it.

10. Substantially Equivalent (SE) Conclusion

Third Party safety testing, adherence to U.S. FDA design control guidance and ISO 14971, as well as thorough in-house, non-clinical (bench) testing and software validation provide reasonable assurance that the **LuminScan™ Imaging System** is safe and effective, and is, with respect to intended use and technological characteristics, substantially equivalent to the predicate device, the **Nvsion VLE Imaging System** under **K112770**.